EXHIBIT 3

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 20, 2015

VIA EMAIL & UPS

Chris Tardio, Esq.
Gideon, Cooper & Essary
315 Deaderick Street, Suite 1100
Nashville, TN 37238

Re: *New England Compounding Pharmacy, Inc. Products Liability Litigation v. Tennessee Clinic Defendants*, MDL 2419, Civil Action No. 1:2013-md-02419

Dear Mr. Tardio:

This letter responds to the third-party subpoena for testimony and production of documents that you issued to the United States Food and Drug Administration ("FDA") in the above-referenced case, dated March 5, 2015, and sets forth our initial objections to the subpoena pursuant to Rule 45(d)(2)(B) of the Federal Rules of Civil Procedure.[1] Per your conversations with Lauren DiPaola, Lead Testimony Specialist in FDA's Office of Policy and Risk Management, the agency is willing to accept service as of March 6, 2015, the date on which you emailed a copy of the subpoena to Ms. DiPaola.

Your subpoena requests testimony pursuant to Federal Rule of Civil Procedure 30(b)(6) regarding a broad range of information going back at least thirteen years, including FDA's "authority to investigate, inspect, regulate, and take action against NECC from 2002 through the meningitis outbreak . . ."; "FDA's internal policies (written or otherwise) . . . and training of staff from 2002" regarding, among other things, "inspection of compounding pharmacies," determining when "regulatory action was appropriate," and "distinguishing between traditional compounding, large-scale compounding . . . , and conventional drug manufacturers"; FDA's decision to "inspect and take action against 30+ compounding pharmacies" "following the meningitis outbreak"; FDA's investigation, inspections, regulation, and actions related to NECC;

[1] Because FDA has not completed its review of potentially responsive documents, this written objection may not include all possible bases for objection. FDA reserves the right to assert at a later time that additional bases exist for objecting to the disclosure of the requested documents and testimony.

information known by the FDA about NECC and whether/how it was made public; FDA's investigation and inspection of, and action against NECC, following the meningitis outbreak; and FDA's views regarding whether "it was the State of Massachusetts' responsibility to take action against NECC . . . ." *See* Subpoena at 2-6.

Your subpoena also requests production of numerous documents, including, but not limited to: all documents (including internal FDA memoranda and communications) "related to FDA's investigation, inspection, and regulation of, and enforcement action against NECC prior to the meningitis outbreak"; FDA's "internal policies, procedures, or training materials" from 2002 related to investigation, inspection, regulation, and enforcement against "large-scale compounding pharmacies" and "how FDA defined a traditional compounding pharmacy versus a large-scale compounding pharmacy acting more similar to a conventional drug manufacturer"; "all of NECC's documents . . . obtained by the FDA in response to the meningitis outbreak"; and all non-privileged documents reviewed by the witness in preparation for giving testimony.

FDA objects to your request for testimony because you have failed to conform to the requirements of the regulation that governs such requests, 21 C.F.R. § 20.1, and objects to your subpoena for the reasons discussed below. Furthermore, based on our initial assessment, it also appears that the Federal Rules of Civil Procedure, federal law, and discovery privileges may prevent FDA from providing the information requested. Below, I explain the grounds for these objections based on our preliminary evaluation.

Requests for FDA Employee Testimony Must
Comport With the Regulation Set Out at 21 C.F.R. § 20.1

With respect to your request for testimony, FDA objects to your request because you have failed to conform to the regulation, 21 C.F.R. § 20.1, that governs requests for the testimony of FDA employees (or meet the standard set forth in the governing regulation). The regulation requires that any person who desires testimony from an FDA employee must submit a written request to the Commissioner with an explanation of: (1) the person's interest in the matter sought to be disclosed; (2) the use to which such testimony will be put in the event of compliance with such request; (3) how the testimony will be in the public interest; and (4) how such testimony will promote the objectives of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the FDA. *See* 21 C.F.R. § 20.1(c); *see also United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 465, 470 (1951). You have not submitted a request for testimony pursuant to 21 C.F.R. § 20.1, nor does your transmittal letter contain the information that would enable the agency to evaluate your request. Additionally, there is an ongoing federal criminal prosecution in the District of Massachusetts involving NECC, and the provision by FDA of testimony or documents has the potential to interfere with that prosecution.

Objection Based on the 100-Mile Limitation

When issuing a non-party subpoena, pursuant to Rule 45(c)(1)(A), "[a] subpoena may command a person to attend a . . . deposition only as follows: (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; [...]". Similarly, Rule 45(c)(2)(A) provides that a subpoena may command "production of documents ... at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person ...." Under Rule 45(d)(3)(A)(ii), a district court must quash or modify a subpoena if it "requires a person to comply beyond the geographical limits specified in Rule 45(c); [...]".

The present subpoena, which was issued by the United States District Court for the District of Massachusetts and served on FDA in Rockville, Maryland, requires FDA, a non-party, to be deposed and produce documents in Nashville, Tennessee. As such, the current subpoena is invalid and unenforceable under Rules 45(c) and (d)(3)(A)(ii).

Prohibition on FDA's Disclosure of Trade Secret and Confidential Commercial Information

FDA is prohibited from revealing trade secret information obtained under certain FDCA provisions except to employees of the Department of Health and Human Services or a court in a judicial proceeding brought under the FDCA. 21 U.S.C § 331(j). In addition, the Trade Secrets Act, 18 U.S.C. § 1905, prohibits the release of trade secret and confidential commercial information (CCI) unless otherwise authorized by law. Further, FDA regulations provide that trade secret information and confidential commercial or financial information are not available for public disclosure. *See* 21 C.F.R. § 20.61. Accordingly, FDA is unable to produce any responsive information that would reveal trade secret and/or confidential research, development, or commercial information. *See also* Fed. R. Civ. P. 45(d)(3)(A)(iii) and (B)(i).

The extent to which the agency will be required to redact responsive documents prior to production, as well as the speed at which FDA will be able to produce these documents, may depend upon whether the parties in the referenced case are authorized and have entered into an acceptable protective order that permits FDA to produce to you potential trade secret and/or CCI that FDA would otherwise need to identify and withhold. In the event that a protective order is not in place, or is inadequate to ensure the protection of trade secret or CCI information belonging to non-parties, you may speed the production of responsive documents, if any, by obtaining an appropriate waiver from the owner of the trade secret or CCI information that

authorizes, with specificity, FDA to provide this information to you for use in the referenced case.

Objections Based on the Deliberative Process and Other Privileges

We expect that some responsive documents may contain information reflecting FDA's pre-decisional deliberative process and are thus privileged and not subject to production under the subpoena. *See* Fed. R. Civ. P. 45(d)(3)(A)(iii). Permitting an FDA employee to be deposed about information that had previously been the subject of internal agency deliberations creates a risk of stifling future agency discourse, which may adversely affect the agency's decision-making process. The privilege extends to, among other things, information "reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *Dep't of the Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (quoting *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975)); *see also Mapother v. DOJ*, 3 F.3d 1533, 1537 (D.C. Cir. 1993). The release of such information would discourage frank and open discussions within the agency and disrupt FDA's ability to engage in the decision-making process. Accordingly, FDA objects to your requests to the extent they seek pre-decisional deliberative information.

Similarly, to the extent that the subpoena seeks disclosure of materials/information that are or contain attorney-client communications, attorney work product, personal privacy information, privileged investigatory files, and/or other protected information, we object to disclosure on those bases as well. The ongoing federal criminal prosecution in the District of Massachusetts involving NECC may also preclude our disclosure of certain material.

The Date of Production Is Unreasonable

Additionally, based on our experience with similar requests, the subpoena as drafted will require a significant amount of time and resources to collect and review potentially responsive documents. Accordingly, FDA objects to your subpoena because it fails to allow a reasonable amount of time to comply. Fed. R. Civ. P. 45(d)(3)(A)(i). Because potentially responsive documents may contain information that is privileged or otherwise protected from release or disclosure, FDA must carefully review every document to determine whether any or all of the information must be withheld from production. The subpoena, however, directs the

production of documents on May 4, 2015, which is insufficient time for FDA to perform its review.

Also, FDA is currently faced with many other voluminous document requests, including Freedom of Information Act and Congressional requests, and is employing a queue approach to the processing of these document requests. Given the existing document production demands on FDA and the time needed to review the potentially large number of documents responsive to your subpoena, directing FDA to respond to your subpoena by May 4, 2015, is unreasonable.

The Subpoena is Overly Broad and Unduly Burdensome

The subpoena is also overly broad and unduly burdensome. *See* Fed. R. Civ. P. 45(d)(3)(A)(iv), (d)(1), (e)(1)(D); 21 C.F.R § 20.50. As noted, your subpoena is quite expansive. It would take many hours of review and preparation for one or more FDA employees to become sufficiently versed in the areas about which you seek testimony, and it would divert those employees from their work on behalf of the agency. Moreover, as discussed above, your requests encompass documents that may contain pre-decisional communications, trade secret, and/or confidential commercial information protected under applicable statutes, regulations, and privileges from release or disclosure. Thus, responding to your subpoena as currently drafted would likely require a significant amount of time to collect and review a large number of potentially responsive documents for possible production. Accordingly, the subpoena is objectionable, pursuant to Rule 45 and 21 C.F.R § 20.50, as overly broad and unduly burdensome.

Conclusion

Notwithstanding the foregoing, FDA is committed to working with you to resolve this matter and to produce documents in a manner consistent with federal law, regulations and procedure and the agency's commitments and obligations in other matters, and without subjecting the agency to an unreasonable burden. Please contact me at (301) 796-8594 if you would like to discuss this matter further.

Sincerely,

Lynn M. Marshall

Lynn M. Marshall
Associate Chief Counsel
Office of the Chief Counsel
U. S. Food and Drug Administration

cc: Lauren DiPaola, Lead Testimony Specialist, FDA